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JUL 10 2006
Amendment
Attorney Docket No. S63.2B-10827-US01

Remarks

This Amendment is in response to the Office Action dated **June 7, 2006**.

Allowable Subject Matter

Claims 72-73 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitation of the base claim and any intervening claim.

Double Patenting

The Office Action asserts that should claim 49 be found allowable, claim 67 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof, referring to MPEP §706.03(k).

Applicant has canceled claim 67.

Applicants have amended claims 68-70, previously dependent from 67, to depend from claim 59. No new matter has been added.

Claim Rejections

35 U.S.C. §103(a)

Claims 59, 62-71 and 74 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Wu et al. (6,254,632) in view of Ruebben (DE 29914243 U1), Edson (US 4,663,005) and Taylor (US 6,558,231).

Applicants traverse the rejection.

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Claim 59 of the present application is directed to a method of cleaning or electropolishing a stent formed from an alloy including at least one noble metal and at least one non-noble metal, the method including, among other steps, the steps of electropolishing the stent in an aqueous acidic mixture including at least one chelating or complexing agent which has at least one sulfur atom *and at least one halide in the form of a salt or an acid and subjecting said acidic mixture to a multiple pulse waveform.*

Applicants submit that there is no motivation to make the combination of Wu et al., Ruebben, Edson and Taylor, and even if there was motivation, Applicants have unexpected and surprising results which are sufficient to rebut a *prima facie* showing of obviousness.

Wu et al., US 6254,632

Applicants submit that Wu et al. disclose providing protruding structures for the surface of a stent. See col. 2, lines 53-55. The stent may be formed from gold (col. 4, lines 43-54) and may be electropolished (col. 12, lines 1-21).

As admitted in the Office Action, Wu fails to suggest that the gold comprise at least one non-noble metal, does not specify the composition of the electropolishing solution and does not specify applying a multiple pulse wave form.

Ruebben, DE 29914243U1

The Examiner employs Ruebben for the gold alloy with a noble metal, i.e. a gold alloy stent formed of gold, palladium, iridium, silver, copper, zinc, tin and ruthenium. See page 3, 3rd paragraph of the Office Action.

The present specification both discloses and claims improved *methods of*

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electropolishing stents which are formed of at least one noble metal and at least one non-noble metal. While Ruebben discloses balloon-expandable endoprosthesis formed from specific high-gold alloys, Ruebben makes no reference whatsoever to electropolishing of the endoprosthesis disclosed therein. Consequently, because Ruebben fails to suggest electropolishing, Applicants would have no motivation to combine Ruebben with Wu et al. Motivation to combine references may come from the nature of the problem to be solved, leading inventors to look to references relating to that problem. See, for example *Pro-Mold and Tool Co. v. Great Lakes Plastics Inc.*, 37 USPQ2d 1626, 1630 (Fed. Cir. 1996). See also Rinehart 531 F.2d 1048, 1054, 189 USPQ 143, 149 (CCPA 1976). Here, however, Ruebben has nothing to do with the problem at hand.

Edson, US 4,663,005

The examiner employs Edson for electropolishing gold alloys in an aqueous acidic mixture comprising thiourea and hydrochloric acid or fluoroboric acid. See page 3, bottom, and 4, top of the Office Action.

As discussed above, claim 59 of the present application is directed to a method of cleaning or electropolishing a stent formed from an alloy including at least one noble metal and at least one non-noble metal, the method including, among other steps, the steps of electropolishing the stent in an aqueous acidic mixture including at least one chelating or complexing agent which has at least one sulfur atom *and at least one halide in the form of a salt or an acid* and subjecting said acidic mixture to a multiple pulse waveform.

Applicants have disclosed that, surprisingly and unexpectedly, “[t]he addition of halides has been found to increase the uniformity of the polishing film or balance its properties to

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provide improved surface finish (smoothness)." Page 11, lines 23-26.

Also, please see part of the specification reproduced below.

Table 5
 Electropolishing

Compound	Range 1	Range 2	Range 3
Sodium Chloride	0-100	20-30	30
Sodium Sulfate (g Na ₂ SO ₄ /L)	0-150	50-150	150
Potassium Cyanide (g KCN/L)	10-100	20-70	30
Glycerol (ml/L)	100-400	200-400	400
Water	Balance 1L	Balance 1L	Balance 1L

In one embodiment according to the invention, polishing was conducted using AC at 1300 ASF. Using the above compositions, cyanide and chloride are present for complexation of the noble metal(s) while the sulfate and water are added for complexation of the active transition metal(s). Glycerol may be added to increase the viscosity of the composition. The addition of a halide salt such as NaCl was found to improve the uniformity of the electropolishing achieved.

See page 16, Table 5, to page 17, lines 1-6 of the present specification.

Applicants submit that Edson discloses an electrolytic process employing a non-toxic electrolytic solution with thiourea and an activating acid which may be selected from methane sulfonic acid, sulfuric acid, hydrochloric acid, phosphoric acid, fluoroboric acid and succinic acid (see Abstract, claim 3 and col. 3, lines 44-47).

There is no disclosure in Edson to add a halide in the form of a salt or an acid in an acidic electropolishing mixture including a chelating agent comprising at least one sulfur atom to increase the uniformity of the polishing film and to balance its properties to provide improved surface finish. See page 10, lines 23-25 of the present specification. While Edson so happens to disclose hydrochloric acid or fluoroboric acid or in the list of possible acids, there is no suggestion that a halide be specifically included in the electropolishing mixture, or that one

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would obtain a better result by doing so. In fact, the preferred acid of Edson is methane sulfonic acid, described by Edson as being "...suitable for the widest range of metals and alloys." Edson discloses that "[c]ertain other acids can be substituted for the methane sulfonic acid obtaining similar results with selected alloys of gold and silver." However, Edson makes no suggestion as to what these "selected alloys" may be, and Edson makes no suggestion that one of skill in the art may get improved polishing of noble metal/non-noble metal alloys as in the present invention if one were to select a halide acid or salt thereof.

Applicants submit that in fact, based on the teachings of Edson, one of ordinary skill in the art would expect the acids listed therein, methane sulfonic, sulfuric, hydrochloric, phosphoric, fluoroboric and succinic acid, to perform equivalently, with the preferred acid, methane sulfonic, giving that performance over a wider range of alloys. There is no basis to believe the halide acid would or could give a better result as is the case in the present invention.

Applicants submit that these are unexpected and surprising results which are sufficient to overcome a *prima facie* showing of obviousness.

Secondary considerations, such as unexpected and surprising results, have long been recognized as being relevant to a determination of obviousness/nonobviousness:

The patent statute provides that "[a] person shall be entitled to a patent unless" any of the Section 102 or 103 bars applies. 35 U.S.C. Section 102. When a chemical composition is claimed, a *prima facie* case of obviousness under Section 103 may be established by the PTO's citation of a reference to a similar composition, *the presumption being that similar compositions have similar properties*. See *In re Dillon*, 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990) (en banc) ("structural similarity between claimed and prior art subject matter, ...where the prior art gives reason or motivation to make the claimed compositions, creates a *prima facie* case of obviousness"), cert. denied, 500 U.S. 904 (1991). One way for a patent applicant to rebut a *prima facie* case of obviousness is to make a showing of "unexpected results," i.e., to show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected. The basic principle behind this rule is straightforward -- that which would have been surprising to a person of ordinary skill in a

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particular art would not have been obvious. The principle applies most often to the less predictable fields, such as chemistry, where minor changes in a product or process may yield substantially different results.

Consistent with the rule that all evidence of nonobviousness must be considered when assessing patentability, the PTO must consider comparative data in the specification in determining whether the claimed invention provides unexpected results. *In re Margolis*, 785 F.2d 1029, 1031, 228 USPQ 940, 941-42 (Fed. Cir. 1986). However, "[i]t is well settled that unexpected results must be established by factual evidence. Mere argument or conclusory statements in the specification does not suffice." *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984); see also *In re Wood*, 582 F.2d 638, 642, 199 USPQ 137, 140 (CCPA 1978) ("Mere lawyer's arguments and conclusory statements in the specification, unsupported by objective evidence, are insufficient to establish unexpected results."); *In re Lindner*, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972)

("[M]ere conclusory statements in the specification...are entitled to little weight when the Patent Office questions the efficacy of those statements.").

In re Soni, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995)(emphasis added). See also *In re Mayne*, 41 USPQ2d 1451, 1454 (Fed. Cir. 1997); *In re Woodruff*, 16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990), and *In re Rouffet*, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998).

Applicants submit that surprisingly and unexpectedly, adding a halide or salt to an acidic electropolishing solution containing a chelating agent comprising at least one sulfur atom, improves the quality of the surface of stents formed from noble enriched metal alloys after polishing when compared to other electropolishing solutions. See page 11, lines 13-32 and also page 16, table 5 and page 17, lines 1-6.

These results are sufficient to overcome a *prima facie* showing of obviousness based on this combination of references.

Taylor, US 6,558,231

The examiner employs Taylor for electropolishing metal using modulated electric fields by applying a pulsed current.

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Applicants submit again, that claim 59 is directed to a method of electropolishing stents formed from noble metal/non-noble metal alloys. Applicants found currently available electropolishing methods to be ineffective for electropolishing of stents enriched with noble metals.

Applicants submit that there is no suggestion by Taylor regarding employing a pulsed current with a noble metal-non-noble metal alloy or employing the process disclosed therein for electropolishing implantable medical devices. In fact, Taylor makes no suggestion whatsoever as to what type of metal the process disclosed therein be used for polishing. As the present invention is directed to electropolishing implantable medical devices formed from noble metal/non-noble metal alloys, there would be no motivation to combine Taylor with Wu et al.

As there is no reason to combine Taylor, Applicants submit that the combination fails to render claim 59 obvious over the combination. Furthermore, even if there was a motivation to combine these references, Applicants showing of unexpected and surprising results is sufficient to overcome any *prima facie* showing of obviousness based on these references.

In summary, the combination fails as Applicants have no motivation to combine either Ruebben or Taylor with Wu et al., which leaves the combination lacking a most important element of claim 1, namely, the multiple pulse waveform.

Furthermore, even if the combination were made, Applicants' unexpected and surprising results of obtaining a smoother stent surface by the addition of a halide in the form of a salt or acid, not suggested by the combination, is sufficient to overcome a *prima facie* showing of obviousness.

Claim 59 is therefore patentable over the art of record.

Claims 61-66 and 68-74 depend from claim 59 and are patentable for at least the

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reasons that claim 59 is patentable over the art of record.

Based on the foregoing, Applicants respectfully request withdrawal of the rejection of claims 59, 61-66 and 68-74 under 35 U.S.C. §103(a) as being unpatentable over Wu (6,254,632) in view of Ruebben (DE 29914243 U1), Edson (US 4,663,00) and Taylor (US 6,558,231).

CONCLUSION

Claims 59, 61-66 and 68-74 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

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Date: July 10, 2006

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